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PEDIATRIC THEME

Informed consent and parental refusal for medical treatment in childhood. The threshold of medical and social tolerance. Part II

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Abstract Medical care in pediatric patients is conditional to parental consent. Parents decide the time and type of treatment they want their children to receive when they are ill. The physician should request parental consent before carrying out the most appropriate therapy. When parents refuse the treatment offered, the physician should seek alternative therapies that may be better accepted by parents and find the most beneficial treatment for children and their families. If physicians and parents are unable to agree on the best therapeutic methods, then the physician becomes involved in an ethical conflict related to the best interests of the child and parental choices. From the above posture, the following questions arise: What should the physician do when faced with this situation? Should the physician use legal measures to force parents to accept treatment? Under what conditions is it justified to force parents and when should the decision be tolerated? What is the role of the Hospital Bioethics Committee concerning this issue? This second part focuses on proposing four practical criteria to be used by the physician and Hospital Bioethics Committee when all alternative therapies and conciliatory options have been exhausted with parents and they continue to refuse treatment. The physician then has to make a decision because the child is placed at risk of harm. This decision focuses on whether there is danger to the minor arising from the decisions of parents and if such harm is avoidable.

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PALABRAS CLAVE

Comités de Ética
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Consentimiento
informado;
Menores de edad

Consentimiento informado y rechazo de los padres al tratamiento médico en edad pediátrica. El umbral de la tolerancia médica y social. Parte II

Resumen La atención médica en pacientes pediátricos está condicionada a la autorización de los padres. Estos deciden el momento y tipo de tratamiento que desean que sus hijos reciban cuando enferman y, bajo su consentimiento, el médico procede a otorgar la terapia más apropiada. Cuando los padres rechazan el tratamiento ofrecido, el médico debe buscar otras alternativas de tratamiento que sean mejor aceptadas por los padres y encontrar el cauce que sea más benéfico para el niño. De no poder conciliar con los padres una terapia, entonces el médico entra en un conflicto ético relacionado con el mejor interés del menor y las decisiones paternas. De lo anterior surgen las siguientes interrogantes: ¿cómo debe actuar el médico cuando enfrenta esta situación?, ¿debe solicitar respaldo jurídico que fuerce a los padres a aceptar el tratamiento?, ¿bajo qué condiciones está justificado obligar a los padres o cuándo debe ser tolerada su decisión? ¿Cuál es papel del Comité de Bioética Hospitalaria en este tema? Esta segunda parte se enfoca en proponer cuatro criterios prácticos para que el médico y el Comité de Bioética Hospitalaria utilicen cuando todas las terapias alternativas y opciones conciliatorias se han agotado con los padres que rehúsan el tratamiento, y cuando el médico tenga que tomar una decisión porque el menor está en riesgo de daño. Dicha decisión gira en torno a si existe peligro evitable para el niño derivado de las decisiones de los padres.

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1. Justification for the State's intervention on the parent's decisions

We present the case of a 1-year-old child with a diagnosis of hepatoblastoma. The oncologists offered treatment based on surgery and chemotherapy with a 50% chance of cure. The parents accepted. Surgical resection of the tumor was carried out and chemotherapy followed. The child received two cycles of chemotherapy each 3 weeks. However, the adverse effects (of the chemotherapy itself) caused the patient great suffering (constant vomiting, headaches, bone pain, sleepiness, fatigue, and epistaxis). For these reasons, the parents requested a rest from the treatment and time to allow them to search for other "alternative" medical treatments that would lessen the child's suffering "without abandoning the current therapy." Due to the child's favorable progression, the oncologists agreed to allow him 4 weeks of rest. The family demonstrated to be committed to the treatment; however, the parents did not return for treatment. Meanwhile, the child received alternative medicine, which included massages, acupuncture, prayers and placing of the hands and oils, as well as organic diet and some antioxidant and regenerative products. He had all possible modes of care. His therapists said that he was healing and, most importantly, that "he was not suffering." However, when the parents brought him back to the hospital, the cancer had advanced and the child died a few months later.

During the broad debate that arose, it was mentioned that the parents did everything humanly and lovingly possible to give their child the best care. Their intention was, above all, the best interests of the child. They never abandoned him, but the physicians argued that the parents were not the only ones who had the ability to decide what was in the child's best interest, and in regard to his health it was

they (the physicians) who had better knowledge. In such a way that if they would have followed with the proposed medical treatment, the child would "probably" still be alive. Some might argue that the attitude of the parents was deplorable and that their ignorance and negligence caused the death of their child, which should be condemned by law. The required question is: Do parents who according to their understanding have done everything humanly possible to cure their child deserve to be punished? Should parents be sanctioned in the same way as parents who refuse treatment for their sick child?

According to the first part of this work, the recommendation is centered in discerning if the decisions of the parents cause severe harm to the child, which could have been avoided. For this, L. Ross states that what is important at the time of deciding if the State's intervention is or is not necessary is that the parents commit abuse, negligence, exploitation, do not cover the basic needs of the child and do not provide the goods, skills, freedoms and opportunities necessary to make them into independent adults able to make and carry out their own life decisions.^{1,2}

A parenthesis needs to be made and once again clarify that the moral and religious conceptions or the beliefs of the parents, no matter how well funded and deeply rooted, are not inherent in the acceptance or rejection of the child's treatment. The rights of the child exercised by the parents are strictly conditioned according to the child's benefit.

Intervention by the State is then justified and should be limited to the cases in which the parents place their children at a potential risk of harm (both physical as well as emotional), which is produced when the children are denied their basic needs.³

According to Diego Gracia: "... that which concerns the State is to monitor non-maleficance, to not harm, and that

which concerns the family and society is beneficence or teaching values to its members in which the State has no intrusion”, the decisions of the parents regarding their children must be in strict benefit and in the exclusive interest of the child.

In this regard, the Bioethics Committee of the American Academy of Pediatrics argues that the intervention by the State should be the last resort, only exercised when it is foreseen, derived from the parent’s decisions, a substantial and great harm to the child such as suffering, direct loss of health and of abilities, or death; similarly, the committee recommends seeking conciliatory pathways with the parents at all times before seeking legal support⁴ because removing the child from the parents would *the last of the viable options*.

Physicians (like any other human beings) have existential conflicts that, facing end situations, could make the lack of resolution and judgment evident for deciding how to act before the parent’s negativity to accept the proposed treatment.⁵ Therefore, the ideal would be to have an orientation on the plan of action to follow when there are cases of treatment refusal, which would represent support in decision making that carries conviction when a resolution is issued. Therefore, bioethics is a tool that should not be overlooked. It is at this point where medical knowledge and personal experience falter and are insufficient for making the best decision.

2. Criteria that justify State intervention

In the case described, at the onset the parents, due to personal reasons, chose a complementary treatment in place of standard treatment. Hypothetically, if the physicians had had the legal authority to force the return of the child to the hospital (over parental objection) and, despite the therapy, the child would have died, then the dilemma would be that having intervened in the decision of the parents had no sense or foundation. The matter would then be “when does the physician intervene in parental decisions?”

The following proposal has at its root the highest interest of the child. This is the reason that moves the physicians to put forth all the necessary resources to avoid harm to the child. But to appeal exclusively to the higher interest will not help, in practice, to decide what concept should prevail, as reported by Diekema and other authors.⁶ What really makes the difference at the time of making the decision whether to intervene legally is to determine if the child is in danger of harm and if this harm is avoidable, which the author calls the “harm principle”.

This type of intervention should be generalized and impartial for all situations in the sense that all similar cases should have a similar outcome and not be impregnated with moral or religious considerations.

The physician who is faced with a pediatric patient with a menacing and serious illness and whose parents reject the proposed treatment has the duty to seek, by all possible means, a conciliatory agreement with the family and offer alternative therapies equally effective to the first proposal. However, these are better accepted by the parents, for example, in the case of anemia with the patient being stable, and therapy is offered with erythropoietin). If an agreement

beneficial to the child is not reached after having exhausted all available resources and if the parents continue to persist in their denial and the child is in danger of harm, then support from the Hospital’s Bioethics Committee should be sought. This will be helpful in making a better decision for the benefit of the child and will evaluate according to consensus the possible legal intervention in the case.

Because of the above, the following four criteria are presented to be considered in cases where treatment is rejected. These are the results of a literature review, of medical experience and discussion of cases of this nature that have been presented before to the Hospital Bioethics Committee of the Hospital Infantil de México Federico Gómez. The purpose of these criteria is to assist physicians in making consensual decisions. They are not laws that must be complied with “to the letter”, so it is recommended to consider them according to the particular situation and to medical judgment. If these criteria are not met, then it would be best to be tolerant of the parent’s decisions and attempt to resolve the conflict in the realm of the physician/patient/parent relationship.

The State should intervene in the following cases:

1. In a situation in which the parents refuse treatment, it is an emergency and the parental decision places the child at immediate risk (here and now). If this is not the case, then the time should be used to look for a conciliatory stance with the parents to arrive at a better solution or treatment option. If, despite this, the parents persist with their *unjustified* refusal and the child is in danger, then legal intervention is justified.

In cases of extreme emergency where a high risk to life exists, physicians have the ability to act for the benefit of the patient even without parental or legal authorization. This is known as therapeutic privilege and is the only exception to informed consent.

2. If the proposed treatment is not experimental, risky, toxic, and has no adverse side effects that can be serious or fatal
3. If the treating physicians can show, in a critical manner and with solid scientific evidence, that the proposed treatment will have a high index of success for the specific disease—treatment may be rejected when it has limited probabilities of success (<50%).
4. If the final outcome and benefit are significantly higher than the option presented by the parents—otherwise, parental decision should be accepted.

If there is no emergency, the first and essential requirement is that the medical staff will have sought, prior and jointly with the parents, an alternative to therapy better tolerated and a mutual agreement, without encouraging results, and that the child is in danger of harm. This is followed by the application of the remaining three criteria.

After analyzing the case and to guarantee the correct intervention from the State, the four criteria should be met. If any are not met, it will be best to tolerate parental decisions in that regard.

For example, if it is a non-urgent case and the physicians have already tried all means available to them to reach an agreement with the parents, but there is no acceptable option and the proposed treatment has a good probability of

success, is not experimental, not risky and its toxic effects are low with few adverse reactions, but the expected result would not be significantly greater to not providing the treatment in question, then there is no cause for legal intervention and it would be convenient to accept the decision of the parents. During the discussion of each case, experts with vast experience in the medical field and ethical aspects should participate to contribute to better decision making.

3. Paradigmatic cases

The following five cases are presented with their respective analysis according to the four criteria proposed for requesting State intervention.

3.1. Case 1

We present the case of AP, an 18-day-old male patient who was diagnosed at 15 days of age with cyanotic congenital heart disease. The patient was referred to the HIMFG during October 2014. The patient was diagnosed with transposition of the great arteries, atrioventricular concordance, and ventriculo-arterial discordance, high trabecular interventricular communication, with interruption of the aortic arch type B and persistent ductus arteriosus. Left ventricular ejection fraction was 65%, decompensated by community-acquired pneumonia. The proposed management by the cardiologists was corrective surgery with a 40% chance of success. The parents, Jehovah Witnesses, desired to continue their son's treatment if and when no transfusions were performed. It was explained to them that during cardiac surgery an extracorporeal pump is used and that there is a risk of complications that would require the use of blood derivatives for resolution. The parents refused. AP died at 72 h after admission because medical management was insufficient to avoid closure of the ductus arteriosus.

AP had a disease that placed his life in danger. If not corrected, he would die in 3 to 5 days. The group of cardiology experts met with the parents to seek a solution, having a maximum of 72 h to reach an agreement. Due to the persistent refusal of the parents, a meeting was requested with the Bioethics Committee at 24 h of admission to support the treating physicians in making the best decision. At the meeting, cardiology experts indicated that the proposed procedure was not free of untoward effects, including death, and although it was not an experimental surgery, the possibilities of success were reduced and subsequent interventions would be required to achieve a total correction.

To "force" the parents to accept any treatment, the medical team must demonstrate, with strong evidence, that the proposed treatment has high probabilities of success. There is an important difference between tested efficacy (based on data and evidence) and medical conviction ("standard of care"). When the physician is attempting to force the parents into accepting an intervention, the medical conviction loses support and only the evidence has value. The burden that is placed on the family from the emotional, cultural and social point of view does not justify the net final benefit. For this reason, the team of experts and members of the

Bioethics Committee decided to accept the parental decision and to not intervene with AP without parental consent.

As in similar cases, there is a direct conflict between two principles: that of religious tolerance towards the parents and that of acting without causing harm to the child. It is understood that the principle of religious freedom resides in autonomy being capable of decision making. The State cannot intervene in the beliefs of persons when they are legal, but those that prevent the child from becoming an autonomous adult with the right to practice any religion or belief are not justified. In these cases, the parents are denying their children this right and impose their religious beliefs upon them; therefore, the harm being making them martyrs of a belief. It is important to make clear that in this case the decision made was not because the parents had a religious belief, but that the medical decision did not offer a greater benefit to the child.

3.2. Case 2

We present the case of NHM, a 1-year 6 months of age female treated since August 2014 and referred due to an abdominal mass. On admission, a thoraco-abdominal computed tomography was done, which reported rounded lesions in the lung parenchyma, hepatomegaly with left lobe lesions and inferior vena cava thrombosis. The patient also had alterations in coagulation and anemia, conditions which prevented a biopsy from being performed on the lesions at that time. The patient remained on outpatient management and tumor markers were requested. Because the parents were practitioners of Jehovah Witnesses, the patient was managed with erythropoietin until the results of the requested tests were available. However, in a few days, the clinical scenario changed with a hepatoblastoma being suspected, a highly malignant lesion with a very poor prognosis. The treating physician presented the case to the Bioethics Committee because the parents did not consent to the necessary transfusions in order to be able to initiate patient treatment.

In the case of NHM, the Bioethics Committee members were in agreement that this was a case which placed life at risk. The parents were not approachable and reluctant to accept a transfusion and surgery for religious reasons. At that time, tumor progression was such that the expert oncologists recommended to not subject the patient to surgery because the prognosis was poor and, despite a successful surgery, the possibility of a 5-year survival was 20%. For this reason, it would not be justified to legally force the parents to accept the proposed treatment. Therefore, it was recommended to accept parental decision and continue with palliative treatment.

The Committee argues that when the treatment offers <40% possibility of success, is risky, toxic and places the life of the child in danger and, in addition, does not offer a significantly beneficial result for the patient, then intervention on the parent's decision is not justified.

3.3. Case 3

JAO, a 12-year-old patient, presented to the Committee June 2014 due to being diagnosed since 2012 with acute myeloid leukemia M4. He was experiencing a second bone

marrow relapse and had already been transplanted with haploidentical hematopoietic stem cells from a related live donor (maternal). He was hospitalized in intensive care due to septic shock. He was presented to the Bioethics Committee because the parents requested to stop treatment because they believed it was without merit. They rejected cardiopulmonary resuscitation maneuvers in case of cardiorespiratory arrest. The oncologists were convinced that, if they continued the treatment, there was still the possibility of a cure. However, the prognosis was uncertain and was very much dependent on whether or not there were infectious complications or of the response to the transplant. Continuation with therapy would include a second infusion of lymphocytes to the patient by the same donor, but the mother (donor) refused to continue with the treatment because it had not produced beneficial results and had caused great suffering to the child, the reason for which the oncologists requested intervention from the Bioethics Committee.

The Committee rejected the oncologists' petition of intervening with the parental decision. The imposed burden had been very high for the patient and family. The therapy provided did not have favorable results and had few real possibilities of success. For this reason, it was requested of the oncologists to respect the decision of the parents and to offer whatever measures that would prevent further suffering of the patient such as transfusions, antibiotics, hydration and nutrition. In this case, no harm towards the child was identified. The parents had been participants of the disease from the diagnosis and had fully contributed (the mother becoming the donor), but there was no improvement and the child's suffering advanced. For these reasons, the Committee considered that their decision was justified and was in the best interest and benefit of the child, even when the result was the death of this patient.

The parents were bound to the *higher interest* standard, with which the eventual will of prolonging the painful process of death or prohibiting sedation if necessary would be *legally invalid*. Prolongation of the dying process and painful agony (by physicians or parents and legal representatives) is contrary to the best interests of the child in objective terms.

Although it was not the case, it has been considered to listen and recognize the mature child (>8 years of age and <18 years of age) the right of rejecting vital treatments even when it supposes facing death, when the possibilities of cure are few and when it is proven and documented that the child is not being influenced or pressured by the parents or by an outsider. If there is doubt, it would be dealt with as if it were a child <8 years of age. Of course, the child is not allowed to reject, in an unjustified manner, a vital medical treatment that implies an increased risk of death.

3.4. Case 4

We present the case of JOL at 10 days of life with history of prematurity (27 weeks of gestation), weight 860 g, and product of cesarean section in a second-level care hospital in December 2013. The patient was referred to the HIMFG due to respiratory, infectious and neurological complications. During his evolution he developed grade II intraventricular hemorrhage and seizures, which worsened the

prognosis. Both parents were informed. One parent desired that treatment be stopped so that the child would not suffer and would not be autonomous. The parent preferred to let him die rather than impose a difficult burden on the child for the rest of his life. The treating physician explained to the parent that with rehabilitation and adequate care the child would be able to have a good quality of life, although with some moderately severe cognitive or motor disorders, which could be overcome with rehabilitation. The parents were also told that neither the physicians nor the parents could deny the child the medical treatment when there are high probabilities of survival. The refusal of the parents to continue treatment was presented to the Bioethics Committee.

Because the neonatologists presented solid scientific evidence that justified the treatment given to the child and guaranteed a favorable quality of life, the Bioethics Committee rejected the parents request to stop treatment for a patient whose probabilities of survival were high.

The treatment offered a net final benefit and surpassed the burdens placed on the child and family. The Committee backed the actions of the physicians in their work of maintaining the wellbeing of the child. There was no need to request legal support because the parents, after being informed of the Committee's decision, agreed to continue with the infant's medical management.

Parents do not wish to cause deliberate harm to their children. Fear of suffering and pain may lead them to make erroneous decisions that could be confused with malfeasance. It is the task of physicians to remove existing doubts to establish a pathway in the relationship with parents that exercise promoting the rights and interests of their child.

3.5. Case 5

We present the case of a patient, ECN, who was 8 years of age and was diagnosed during February 2007 with vertically transmitted AIDS C3. From the time of diagnosis, the patient's attendance at the HIMFG was very irregular. The mother does not administer antiretrovirals to the patient or to herself. This has caused multiple hospital admissions due to infectious complications of such severity that they always required management in the intensive care unit. During the last hospital attendance of the patient, he reported that he had not received any medication for 3 months in addition to not having arrived at any of his appointments. The patient's current diagnosis includes AIDS C3, interstitial lymphoid pneumonitis, pulmonary hypertension, and therapeutic failure. The most recent viral load for HIV was 128,260 copies/ml; subpopulation of lymphocytes CD4+ was 26 cells/ μ l.

Although family members have pledged to help the child, this has not been accomplished. The treating physicians are extremely concerned about the future of ECN and requested a meeting of the Hospital Bioethics Committee. The Committee noted that the physicians were interested in the wellbeing of ECN. They had previously reported the case to the abuse clinic due to negligence in care and treatment, but without a response. The harm that the mother is causing her son increases over time, in addition to being irreversible. The physicians have invested much time in reaching an agreement with ECN's mother and have sought multiple ways of convincing her to administer the medications to her

son. The alternative offered by the mother is to not administer any treatment and allow the disease to take its natural course, which is contrary to the wellbeing of ECN and his rights.

Antiretroviral therapy, without a doubt, would guarantee both mother and child a better quality of life and less disease progression. If therapy is not administered, death will come quickly and aggressively. Rejection of treatment for the child was unjustified because it has been demonstrated to be effective and not risky. The final benefit is significantly higher than to not administer antiretroviral treatment. Refusal to administer anti-retrovirals should not be tolerated.

The Committee recommended legal intervention in this case to assure a better pathway that would guarantee the wellbeing of ECN, even when this decision means total or partial removal of custody.

These five cases exemplify that parental decisions usually have their origin in the wellbeing of their children. There will be occasions where such decisions are contrary to medical opinion. Medical personnel must evaluate and analyze each situation in light of the best interest of the child and offer an opinion of tolerance or rejection with respect to the medical decisions that the parents make for their children.

The interest of the child in all circumstances must prevail or be superior to any other course. Both the physician and the parents must seek resolutions for the highest benefit of the child. The criteria of highest interest of the child in practice is less clear at the time of deciding if one should or should not act legally.

Intervention by the State should be reserved as a last resort effort in those cases in which no conciliatory agreement

can be reached with the parents and there is imminent risk or harm to the child as a result of rejection of medical treatment, as well that this danger is believed to be preventable with the proposed treatment.

On developing the analysis of each case, it is proposed that the four criteria be implemented to assist the medical staff in making their decision of whether legal intervention is justified and that preferably will be requested when the proposed criteria are met. If any of these is absent, then the recommendation will be to accept the parental decision and to not propose legal intervention.

Conflict of interest

The authors declare they have no conflicts of interest.

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